

AUG 29 1996

510(k) Summary

- a.1. Diagnostic Hybrids, Inc.
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Athens, OH 45701
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Attn.: J.L. Brown
Date of Preparation: July 12, 1996
- a.2. Trade Name: **FreshFrozen Cells™**
Classification Name: Cells, Animal and Human, Cultured.
- a.3. A predicate device is that of BioWhittaker, marketed as cell cultures, Cryopreserved ampules, Appendix II, p.19 of this 510(k) Notification.
- a.4. The subject device provides frozen HEp-2 cells in measured quantities allowing the user to simply thaw and dilute the cells to a prescribed volume, plant prescribed volumes in appropriate containers and after a few days, the cell monolayers will be confluent and ready to use for virus isolation and identification.
- a.5. Intended Use: Cell cultures to be used for specific virus isolation and identification. The subject of this 510(k) Notification, the cell line, HEp-2, is susceptible to and can be used in the isolation and confirmation of the following viruses from clinical samples:

Adenovirus	Parainfluenza
HSV	Poliovirus
Coxsackie B	RSV
Measles	

- a.6. A comparison of Technological Characteristics:

<u>Characteristics</u>	<u>Predicate Device</u>	<u>Subject Device</u>
Source of Cell Line	ATCC or another approved supplier.	Same as predicate device.
Provided Frozen	Cells can be stored frozen for months prior to thawing for use.	Same as predicate device.
Intended Use	Isolation & Confirmation of specific viruses.	Same as predicate device.

- b.1. The non-clinical tests consist of those used to characterize the product such as appearance, growth characteristics, sterility, isoenzyme analysis and virus susceptibility.
- b.2. Not Applicable.
- b.3. Not Applicable.